

**REMARKS**

**I. STATUS OF THE CLAIMS**

Claims 12, 15, 18, 27, 28, 30, 33-36, 40, 41, 44-47, and 51-54 are pending and under examination. Applicants have canceled claims 17, 29, 31, 32, 37-39, 42, 43, and 48-50 without prejudice or disclaimer of the subject matter of those claims. Applicants have added new claims 53 and 54. Claims 12, 18, 27, and 30 are amended to indicate that "component (B) is present in a proportion of 5 to 500 parts by weight per 100 parts by weight of component (A)." Claims 34, 41, 45, and 52 are amended to recite "(A) ascorbic acid 2-glucoside." Claims 35 and 46 are amended to indicate that "component (B) is 0.1% to 7% (w/w) based on the total amount of the composition." Support for the amended and new claims can be found throughout the specification, for example at page 4, lines 18-21; page 5, lines 18-21; page 9, lines 14-23; page 11, lines 13-18; page 12, lines 19-23; and page 14, lines 5-9 and Example 1 of the as-filed specification. Accordingly, no new matter is added.

**II. REJECTIONS UNDER 35 U.S.C. § 103**

**A. *Wakamatsu* in View of *Castiel***

The Office rejects claims 12, 15, 17, 18, and 31-41 under 35 U.S.C. § 103(a) as allegedly obvious over WO 02/41853 to *Wakamatsu et al.* ("*Wakamatsu*") in view of U.S. Publication No. 2002/0042380 to *Castiel et al.* ("*Castiel*"). Office Action, p. 3. Applicants address this rejection with respect to claims 12, 15, 18, 33-36, 40, and 41, which are still pending.

According to the Office, *Wakamatsu* teaches an oil-in-water (O/W) emulsion comprising an electrolyte, where the preferred electrolytes are adenosine

monophosphate, cyclic adenosine monophosphate, salts thereof, ascorbic acid, and derivatives thereof. *Id.* *Wakamatsu* also allegedly teaches that adenylic acid derivatives have anti-aging effects when applied to the skin, and that electrolytes can be used alone or in combination of two or more species. *Id.* at pp. 3 and 4. The Office acknowledges that *Wakamatsu* does not teach compositions comprising ascorbic acid 2-glucoside or that ascorbic acid 2-glucoside is an acceptable ascorbic acid derivative. *Id.* at p. 4. The Office also acknowledges that *Wakamatsu* does not teach a method of potentiating the anti-aging effect of ascorbic acid 2-glucoside by adding AMP or a method of retarding skin aging. *Id.* Applicants note that the Office appears to describe independent claim 18 as a "method applying the herein claimed composition to the skin to prevent aging." *Id.* Applicants note that claim 18 in fact recites a "method for retarding skin-aging."

The Office applies *Castiel* for its alleged teaching of vitamin C derivatives with improved stability for combating intrinsic aging of the skin. *Id.* According to the Office, *Castiel* lists ascorbic acid 2-glucoside as one of the preferred ascorbic acid derivatives and teaches that ascorbic acid 2-glucoside is a known depigmenting agent. *Id.* at pp. 4-5.

The Office contends that one of ordinary skill in the art would have been motivated to combine the AMP derivatives of *Wakamatsu* with the ascorbic acid derivatives of *Castiel* because the references allegedly teach that AMP derivatives and ascorbic acid derivatives are used for the same purpose, namely to keep skin from aging. *Id.* at p. 5. The Office also contends that one of ordinary skill in the art would have expected that the combination of ascorbic acid 2-glucoside and adenosine

monophosphate would have “up to an additive effect.” *Id.* Thus, the Office concludes that it would have been obvious to combine the alleged teachings of *Wakamatsu* and *Castiel* to arrive at the method of claims 12, 15, 17, 18, and 31-41.

In response to Applicants' previous arguments, the Office asserts that *Castiel* sufficiently motivates one of ordinary skill in the art to select ascorbic acid 2-glucoside for combination with *Wakamatsu*'s adenosine monophosphates (“AMPs”) because *Castiel* teaches that ascorbic acid derivatives may be administered for combating intrinsic aging of the skin, and that ascorbic acid 2-glucoside is a preferred ascorbic acid derivative. *Id.* at p. 9. The Office also asserts that the mechanism of action of each component does not detract from the alleged expectation that the combination would produce an *additive effect*, since both components are used individually in the art to keep skin from aging, and combination therapy is often employed using components that act via different mechanisms. *Id.* at p. 10. Finally, the Office again alleges that the evidence of synergism demonstrated in the specification is not commensurate with the breadth of the claims. Specifically, the Office argues that a single example with a specific amount of each component does not provide sufficient evidence that the remaining compositions possible under the claim scope would exhibit the same or similar results. *Id.* at p. 11. Applicants respectfully disagree and traverse the rejection for the reasons of record and the following additional reasons.

Several basic factual inquiries must be made to determine whether the claims of a patent application are obvious under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), require the Office to:

- (1) Determine the scope and content of the prior art;

- (2) Ascertain the differences between the prior art and the claims in issue;
- (3) Resolve the level of ordinary skill in the pertinent art; and
- (4) Evaluate evidence of secondary considerations.

The obviousness or non-obviousness of the claimed invention should then be evaluated in view of the results of these inquiries. *Graham*, 383 U.S. at 17-18; *see also* *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007). "To reach a proper determination under 35 U.S.C. § 103, the Examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." M.P.E.P. § 2142, 8<sup>th</sup> Ed., July 2008 Rev. Once the findings of fact are articulated, the Office "must then make a determination whether the claimed invention 'as a whole' would have been obvious at the time to that person." *Id.*

The Office has yet to establish a *prima facie* case of obviousness here because the Office has not shown that one of ordinary skill in the art would have predicted, based on the cited references, that the combination of an AMP and ascorbic acid 2-glucoside would potentiate the antiaging action of a composition containing ascorbic acid 2-glucoside, retard skin aging, or alleviate skin pigmentation as recited in the rejected claims. The Office contends that "the combination of ascorbyl 2-glucoside and adenosine monophosphate used for the same purpose of anti-aging action, is expected to have up to an additive effect." Office Action, p. 5. Applicants respectfully remind the Office, however, that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some

rational underpinning to support the legal conclusions of obviousness.” M.P.E.P.

§ 2142 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *see also KSR*, 127 S. Ct. at 1741 (quoting Federal Circuit statement with approval). Here, the Office has not articulated a reason to support the conclusion that one of ordinary skill in the art would have expected the combination of an AMP and ascorbic acid 2-glucoside to produce additive results.

With respect to claims 34 and 41, the Office effectively ignores the concept of synergism as reflected in these claims. Specifically, the Office either fails to address this concept entirely or provides an argument for rejection based on whether there is an additive effect. The Office's discussion of whether or not an additive effect would be expected does not address the synergistic effect demonstrated by the invention. As the M.P.E.P. instructs, “[e]vidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating ‘synergism’) ....” Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent.” M.P.E.P. § 716.02(a)(I). Even if one of ordinary skill in the art would have expected an additive effect, as the Office suggests, synergism goes beyond an additive effect and would not have been expected. Specifically, as Applicants noted previously, because AMP and ascorbic acid work by different mechanisms, one would not have expected a synergistic effect when combining the two.

Regarding the Office's belief that the specification's demonstration of synergy is not commensurate in scope with the rejected claims, Applicants note that the Office has not explained why it believes that other concentrations of AMP and ascorbic acid 2-

glucoside would not also demonstrate synergy. However, solely to facilitate prosecution and without acquiescing to the rejection, Applicants have amended claims 12, 18, and 30 to indicate that "component (B) is present in a proportion of 5 to 500 parts by weight per 100 parts by weight of component (A)" and amended claim 35 to indicate that "component (B) is 0.1% to 7% (w/w) based on the total amount of the composition." These proportions of components (A) and (B) are included in the proportions described in Test Example 1 and the other Examples of the specification.

Indeed, the references cited by the Office fail to provide any guidance as to whether the effect of combining an AMP with ascorbic acid 2-glucoside will be, *e.g.*, (1) synergistic (*i.e.*, greater than the additive effect of the components when administered together), (2) antagonistic (*i.e.*, less than the effects of the components when administered alone), (3) additive (*i.e.*, equal to the sum of the effects of the components when administered alone), or (4) sequence-dependent (*i.e.*, the order in which the components are given governs their effects). Thus, based on the cited references one of ordinary skill in the art would not have predicted that the combination of an AMP and ascorbic acid 2-glucoside would produce "up to an additive effect," as alleged by the Office, let alone the synergistic effect demonstrated in the specification. See Figure 1.

In sum, the instant application demonstrates for the first time that combining AMP with a composition containing ascorbic acid 2-glucoside potentiates the effects of ascorbic acid 2-glucoside. Neither *Wakamatsu* nor *Castiel*, alone or in combination, would have led one of ordinary skill in the art to predict this aspect of the invention. When a patent application claims a combination of elements that work together in an unexpected and fruitful manner, the invention would not have been obvious. See *KSR*,

127 S. Ct. at 1740 (2007). For at least these reasons, the Office has failed to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**B. *Wakamatsu* and *Castiel* in View of *Quan***

The Office rejects claims 27-30 and 42-52 under 35 U.S.C. § 103(a) as allegedly obvious over *Wakamatsu* and *Castiel* in view of U.S. Patent No. 6,180,133 to Quan et al. ("*Quan*"). Office Action, p. 6. Applicants address the rejection with respect to claims 27, 28, 30, 44-47, 51, and 52, which are still pending.

The Office uses *Wakamatsu* and *Castiel* as discussed above. Acknowledging that *Wakamatsu* and *Castiel* do not teach potentiating a skin pigmentation alleviating action of a composition comprising ascorbic acid 2-glucoside or alleviating skin pigmentation, the Office points to *Quan* for allegedly teaching that aging of the skin "may be characterized by wrinkling of the skin, uneven or hyperpigmentation, loss of distensibility, and uneven texture ...." *Id.* at p. 7. Because *Quan* allegedly teaches that hyperpigmentation of the skin is a sign of aging, the Office concludes that it would have been obvious to potentiate a skin pigmentation alleviating effect by adding adenosine monophosphate to ascorbic acid 2-glucoside based on the teachings of *Wakamatsu* and *Castiel*. See *id.* According to the Office, one of ordinary skill in the art would have been motivated to make a composition for treating skin pigmentation and would have had a reasonable expectation of success because *Wakamatsu* and *Castiel* allegedly teach that AMP and ascorbic acid 2-glucoside have anti-aging action, *Castiel* allegedly teaches that ascorbic acid 2-glucoside is a skin depigmenting agent, and *Quan* teaches skin aging is characterized by uneven and/or hyperpigmentation. See *id.* Applicants

respectfully disagree and traverse the rejection for the reasons of record and the following additional reasons.

As noted above, the combination of *Wakamatsu* and *Castiel* fails to teach or suggest the unexpected results demonstrated in the instant application. Specifically, with respect to claims 27, 28, 30, 44, 46, 47, and 51, *Wakamatsu* and *Castiel* fail to provide any reason for one skilled in the art to have predicted that combining AMP with a composition containing ascorbic acid 2-glucoside would potentiate the skin pigmentation alleviating action of the composition containing ascorbic acid 2-glucoside or that applying ascorbic acid 2-glucoside and AMP to pigmented skin would alleviate skin pigmentation, as recited in those claims. *Quan* cannot cure this deficiency in *Wakamatsu* and *Castiel*, because *Quan* does not teach or suggest these aspects of the claimed invention. Since the instant application claims a combination of elements that work together in an unexpected and fruitful manner, the invention would not have been obvious. See *KSR*, 127 S. Ct. at 1740 (2007).

As for claims 45 and 52, the Office has not addressed the concept of synergistic potentiation in this rejection. Synergy goes beyond the simple additive effect of two components.

For at least the reasons set forth above, the Office has failed to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the rejection be withdrawn.



**III. CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of claims 12, 15, 18, 27, 28, 30, 33-36, 40, 41, 44-47, and 51-54.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By: \_\_\_\_\_

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